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J. Kern Buckner

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EXAMINER

PORTER, JR, GARY A

ART UNIT

PAPER NUMBER

3766

NOTIFICATION DATE

DELIVERY MODE

11/19/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

efspatents@sbiplaw.com

Office Action Summary	Application No. 10/599,662	Applicant(s) BUCKNER ET AL.	
	Examiner GARY A. PORTER, JR	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,4,44,46 and 59-62 is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 43,75 and 89 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1,2,4,5,7,13-15,17,29,34,36,40,43,44,46,59-62,68,69,71,75,78,80,89 and 90.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The Examiner notes that in response to the previous 112 rejection on the means for language (see Action mailed 5/12/2009), Applicant specifically stated that the structure meant to be incorporated by the "means for" language was in paragraphs [0067] and [0076] of the PG PUB of the application (2008/0027268). From this admission, the Examiner has associated the curved longitudinal bands 30-33 of paragraph [0067] with the "means for" limitation. This is supported by paragraph [0076] which states that the bands assume stable contracted and expanded states, which correspond to end systolic diameter and end diastolic diameter, respectively. With this interpretation, the 112 rejection of Claim 1 is withdrawn.
2. If this is not the exact structure Applicant intended to incorporate with the "means for" language, the Examiner suggests specifically stating on the record the exact structure Applicant wishes to incorporate into Claim 1 by the "means for" language.
3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 2, 5, 7, 13-15 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Regarding Claim 2, claim element "means operatively associated with the frame for limiting the ventricle to a select end diastolic internal diameter" is a means (or step)

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plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to clearly link or associate the disclosed structure, material, or acts to the claimed function such that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function. Specifically, Applicant, in Claim 1, has already claimed the curved longitudinal bands 30-33 of paragraph [0067]. Furthermore, according to paragraph [0076], these curved bands also apply a restrictive force during diastolic expansion. Therefore, it is unclear what structure, other than the bands, provides this restrictive force. If, as the Examiner believes, the curved bands perform the functions of Claim 1 and 2, then Claim 2 is objected to as failing to further limit the parent Claim. The Examiner suggests either clarifying which structure is intended via the options below or canceling the claim since it does not add any new structure to independent Claim 1.

6. Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it clearly links or associates the corresponding structure, material, or acts to the claimed function without introducing any new matter (35 U.S.C. 132(a)); or

(c) State on the record where the corresponding structure, material, or acts are set forth in the written description of the specification that perform the claimed function.

For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

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7. The claim limitation “assisting means...for” in Claim 1 uses the phrase “means for” or “step for”, but it is modified by some structure, material, or acts recited in Claim 5, 7, 13-15 and 17.

8. If applicant wishes to have the claim limitation treated under 35 U.S.C. 112, sixth paragraph, applicant is required to amend the claim so that the phrase “means for” or “step for” is clearly **not** modified by sufficient structure, material, or acts for performing the claimed function.

9. If applicant does **not** wish to have the claim limitation treated under 35 U.S.C. 112, sixth paragraph, applicant is required to amend the claim so that it will clearly not be a means (or step) plus function limitation (e.g., deleting the phrase “means for” or “step for”).

10. Furthermore, it appears that Applicant is claiming the curved bands of paragraph [0067], which are bistable elements that provide assistance to an end systolic diameter and end diastolic diameter (paragraph [0076]. If this is the case, Claim 5 fails to further limit parent Claim 1 and therefore should be cancelled. Only when new, separate structure is defined should the claim remain.

11. The only other interpretation the bistable element could be is the entire assembly 10 as stated in paragraph [0067] and Fig. 1. If this is the desired interpretation, the Claims as currently structured are improper. Specifically, Claim 1 recites an apparatus comprising individual components. Claim 5, therefore would be requiring the individual longitudinal bands 30-33 to contain as bistable element, which a stated in paragraph [0067] is the entire assembly 10. It would be impossible for a subassembly to consist of

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an assembly. The assembly must consist of the subassembly, not the reverse. Further clarification of the structure intended to be incorporated in Claim 5 is required.

12. Claim 7 is indefinite for further adding to the confusion of the intended structure to be incorporated by the “means for” language of Claim 1. As per Applicant's response, the “means for” language appears to incorporate the curved longitudinal bands 30-33 of paragraph [0067]. However, Claim 7 claims this structure, which in effect has already been incorporated into Claim 1. Therefore, either Claim 7 should be cancelled since it fails to further limit parent Claim 1 or Applicant should specifically clarify the exact structure each “means for” statement is intended to incorporate.

13. Claims 13, 14, 15 and 17 further add confusion to the structure intended to be claimed and require the same level of clarification as that of Claim 7.

14. In summary, the structure of apparatus incorporated in Claims 1, 2, 4, 5, 7, 13-15 and 17 is vague and unclear. The use of “means for” in Claim 1 that incorporates the structure of paragraphs [0067] and [0076] seems to be contradictory to the limitations recited in subsequent dependent claims. If the “means for” is intended to incorporate the curved longitudinal bands 30-33 (of paragraph [0067]) then Claims 2, 5, 7 and 17 fail to further limit Claim 1. If this is not the case, further clarification is need on the record for identifying the intended structure.

15. Lastly, to help clarify the exact structure the “means for” statement incorporates, the Examiner suggests amending the specification to explicitly state, “the assisting means operatively associated with the frame for mechanically assisting movement is **X**.”

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Such an amendment would incorporate the claim language to explicitly tie the structure of the specification to the Claim.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 29 is rejected under 35 U.S.C. 102(b) as being anticipated by Melvin et al. (2003/0023132).

17. Regarding Claims 29 and 90, Melvin discloses disposing a frame within a chamber of the heart, i.e. the ventricle, and storing energy in its springs during systolic ejection (Section [0091]; Fig. 19). This energy is released during diastole to enhance diastolic filling (Section [0092]). Melvin further discloses that restraining bars 111 limit the end diastolic and systolic volumes (Sections [0083, 0092]).

18. In regards to Claim 90, Applicant claims structure without positively reciting a method step. Therefore, the apparatus only has to be capable of limiting the end diastolic diameter. With this interpretation, the device taught by Melvin meets this limitation since the elasticity of bars 11 limit the end diastolic and systolic volumes (Sections [0083, 0092]).

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

21. Claims 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Melvin et al. (2003/0023132) in view of Feld et al. (2004/0002626). Melvin discloses disposing a frame within a chamber of the heart, i.e. the ventricle, and storing energy in its springs during systolic ejection (Section [0091]; Fig. 19). This energy is released during diastole to enhance diastolic filling (Section [0092]). Melvin further discloses that restraining bars 111 limit the end diastolic and systolic volumes (Sections [0083, 0092]). Melvin does not disclose a loop shaped strap for connecting together the spring elements 721 to form a more rigid structural frame. However, Feld describes a framework having longitudinal elements 12" for placement within a heart chamber (Fig. 3b-5b). Lacking any criticality, it would have been an obvious substitution to replace the apical end 730 of Melvin with a connecting ring 14 as described by Feld in Fig. 5b, since both configurations perform the same function of linking the distal portions of each longitudinal element together.

22. Claims 36, 68, 69, 71, 78 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Melvin et al. (US Pub. 2003/0023132) in view of Feld et al. (US Pub. 2004/0002626), further in view of Cloud (US Patent 5,184,482).

23. Regarding Claim 36, the Melvin and Feld combination discloses all of the claimed invention except for forming the circular band with a circumferential ligature, wherein the ends of the ligature are tied together to form a ring. However, Cloud teaches forming a loop with a resilient material, i.e. a spring metal material, by attaching free ends of the material together (col. 7, lines 40-59). Although Cloud is merely teaching the formation of ear ornaments, the act of tying or connecting free ends of a resilient material together in order to form a loop is illustrated, therefore illustrating that such a method step of formation is not novel. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device in the Melvin and Feld combination to include tying two ends of a material, i.e. spring metal, together, as taught and suggested by Cloud, for the purpose of creating a resilient ring formation.

24. In regards to Claims 68, 71, 78 and 80, Melvin discloses disposing a frame within a chamber of the heart, i.e. the ventricle, and storing energy in its springs 721 during systolic ejection (Section [0091]; Fig. 19). This energy is released during diastole to enhance diastolic filling (Section [0092]). Melvin further discloses that restraining bars 111 limit the end diastolic and systolic volumes (Sections [0083, 0092]). Melvin does not disclose a loop shaped strap for connecting together the spring elements 721 to form a

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more rigid structural frame. However, Feld describes a framework having longitudinal elements 12" for placement within a heart chamber (Fig. 3b-5b). Lacking any criticality, it would have been an obvious substitution to replace the apical end 730 of Melvin with a connecting ring 14 as described by Feld in Fig. 5b, since both configurations perform the same function of linking the distal portions of each longitudinal element together. Additionally, the Melvin and Feld combination discloses all of the claimed invention except for forming the circular band with a circumferential ligature, wherein the ends of the ligature are tied together to form a ring. However, Cloud teaches forming a loop with a resilient material, i.e. a spring metal material, by attaching free ends of the material together (col. 7, lines 40-59). Although Cloud is merely teaching the formation of ear ornaments, the act of tying or connecting free ends of a resilient material together in order to form a loop is illustrated, therefore illustrating that such a method step of formation is not novel. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device in the Melvin and Feld combination to include tying two ends of a material, i.e. spring metal, together, as taught and suggested by Cloud, for the purpose of creating a resilient ring formation.

25. In regards to Claim 69, Melvin discloses all of the claimed invention except for the exact material used to form the band and spring element. However, the Examiner notes it would have been obvious to one having ordinary skill in the art at the time the invention was made to use biocompatible materials for the implanted devices, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design

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choice. *In re Leshin*, 125 USPQ 416. Furthermore, such design consideration is well known in the art, as evidenced by Ferrazzi (2003/0158570) in paragraph [0082].

26. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Melvin et al. (US Pub. 2003/0023132) in view of Stevens et al. (US Patent 6,125,852). Melvin discloses all of the claimed invention except for performing a surgical ventricular reduction. However, Stevens teaches that it is known in the art to perform a ventricular reduction on a congestive heart failure patient in order to reshape the enlarged heart to a normal size (Abstract; Fig. 3-5). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method in the Melvin reference to include performing a ventricular reduction, as taught and suggested by Stevens, for the purpose of reshaping an enlarged heart to a normal size.

Allowable Subject Matter

27. Claims 1, 4, 44, 46, 59, 60, 61 and 62 are allowed.

28. Claims 43, 75 and 89 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

29. The following is a statement of reasons for the indication of allowable subject matter: The prior art does not contain a teaching of a bistable element that forces the ventricle to assume a specific end systolic diameter and end diastolic diameter. The prior art only teaches non-stable, elastic elements that aid in systolic contraction but

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only passively limit end diastolic diameter without actively assisting in diastolic expansion.

30. Lastly, the prior art relied upon in the rejections above to not teach or disclose a need for a mitral annuloplasty ring.

Response to Arguments

31. Applicant's arguments filed 8/12/2009 regarding the rejection of Claim 29 as being anticipated by Melvin et al. (2003/0023132) have been fully considered but they are not persuasive. As stated in the rejection above, the Melvin reference teaches limiting the diastolic volume through the elastic properties of pressure-transfer mechanism 723 (Section [0083,0092]).

32. Applicant's arguments, see pages 11-14, filed 8/12/2009, with respect to the rejection of Claims 1-4, 20, 26, 29, 34, 43, 59, 60, 68, 69, 71, 75, 78 and 89 as being anticipated by Ferrazzi (2003/0158570) have been fully considered and are persuasive. The rejection of the claims has been withdrawn.

33. Applicant's arguments with respect to claim 34 have been considered but are moot in view of the new ground(s) of rejection.

34. Applicant's arguments filed 8/12/2009 regarding the rejection of Claim 40 over Melvin in view of Stevens have been fully considered but they are not persuasive. Melvin does teach implanting within the ventricle of a heart and apparatus that limits systolic contraction and diastolic expansion via the elastic properties of bands 111 and springs 721 (Sections [0082, 0093]).

Conclusion

35. To move this case forward, the Examiner urges Applicant to address the 112 issue presented in apparatus claims 2, 4, 5, 7, 13-15 and 17. Confusion exists about the exact structure Applicant is claiming. Clarification on the record and possibly amendments to the specification are required.

36. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GARY A. PORTER, JR whose telephone number is (571)270-5419. The examiner can normally be reached on Monday - Thursday, 7AM - 4PM EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571)272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/G. A. P./
Examiner, Art Unit 3766

/Carl H. Layno/
Supervisory Patent Examiner, Art
Unit 3766